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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DOUGLAS C. SHEPARD

Appeal 2008-0401
Application 10/057,596
Technology Center 1600

Decided: January 3, 2008

Before TONI R. SCHEINER, DONALD E. ADAMS, and NANCY J. LINCK, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 11-24, and 27, the only remaining claims (claims 2-10, 25, 26, and 28-32) "were withdrawn from consideration pursuant to a requirement for restriction and election of species" (Br. 2). We have jurisdiction under 35 U.S.C. § 6(b).

INTRODUCTION

The claims are directed to an enzymatically active medical article (claims 1 and 11-22) and a therapeutic method comprising the use of the article (claims 23, 24, and 27). Claim 1 is illustrative:

> 1. An enzymatically active medical article comprising:
> a medical article having a matrix disposed on said article, wherein the matrix comprises block copolymer comprising a polyolefinic block comprising polybutylene and a thermoplastic block comprising polymers of acrylates, methacrylates or vinyl aromatics, an enzyme disposed within said matrix and at or near a surface of said medical article, such that said medical article is provided with an enzymatically active surface, wherein said matrix allows diffusion of substrates into and diffusion of products out of the matrix, wherein said enzyme is selected from the group consisting of protease enzymes, glycosidase enzymes, enzymes that degrade oxalate, and enzymes that generate NO from arginine.

The Examiner relies on the following prior art references to show unpatentability:

Hendrickson	US 4,855,234	Aug. 8, 1989
Pinchuk	US 5,741,331	Apr. 21, 1998
Van Antwerp	US 5,788,678	Aug. 4, 1998
Sivan	US 6,569,688 B2	May 27, 2003

The rejections as presented by the Examiner are as follows:

1. Claims 1, 13-16, and 19-24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hendrickson and/or Van Antwerp taken with Pinchuk.

2. Claims 17 and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hendrickson and/or Van Antwerp taken with Pinchuk and Appellant's admitted prior art.[1]

3. Claims 1, 11-16, 19-24, and 27 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Sivan and Pinchuk.

4. Claims 17 and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Sivan, Pinchuk, and Appellant's admitted prior art.

We reverse.

DISCUSSION

Claim interpretation:

Claim 1 is drawn to an enzymatically active medical article. According to Appellant's Specification a medical article includes a catheter. (Specification ¶ 22). The medical article comprises:

A. a matrix disposed on a medical article (e.g., a catheter) that allows diffusion of substrates into and diffusion of products out of the matrix; and

B. an enzyme disposed within the matrix and at or near a surface of the medical article such that the medical article is provided with an enzymatically active surface.

Claim 1 requires that the matrix comprises a block copolymer comprising a polyolefinic block. The polyolefinic block comprises:

i. polybutylene; and

[1] The Examiner includes a citation to Forster, Am. J. Surg., 156(2): 130-32 (1988) in this ground of rejection. We note, however, that the Examiner expressly states that the Forster reference was "withdrawn from the rejections" (Answer 2). Accordingly, we find the Examiner's reference to Forster to be an artifact of the prosecution on this record. Therefore, we have not included the Forster reference as part of our deliberations.

ii. a thermoplastic block comprising polymers of acrylates, methacrylates, or vinyl aromatics.

Claim 1 further requires that the enzyme is selected from the group consisting of protease enzymes, glycosidase enzymes, enzymes that degrade oxalate, and enzymes that generate NO from arginine.

Claims 13-16 and 19-22 depend directly or indirectly from claim 1. Method claims 23, 24 and 27 require the use of the article of claim 1.

Obviousness:

Claims 1, 13-16, and 19-24 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hendrickson, Van Antwerp and Pinchuk.

The Examiner finds that Hendrickson teaches a device that has a polymer coating and the enzymes catalase and papain immobilized on its surface (Answer 3). The Examiner finds that Van Antwerp teaches a medical article (a catheter) that has fibrinolytic enzymes encapsulated and bonded to the surface of the catheter (*id.*). The Examiner recognizes, however, that neither reference teaches "the use of [the] claimed block copolymer comprising polybutylene and acrylates or vinyl aromatics" (*id.*).

The Examiner relies on Pinchuk to make up for the deficiency in Hendrickson and Van Antwerp. According to the Examiner, Pinchuk teaches that medical devices made from block copolymers of polyolefin and styrene or acrylate are "biostable and crack-resistant when implanted in vivo" (Answer 4).

Based on this evidence the Examiner concludes that

> [t]he use of polymeric material made from block copolymers of polyolefin and styrene or acrylate in the medical devices if [sic] Hendrickson or [Van] Antwerp would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.

(*Id.*)

In response Appellant asserts that the Examiner failed to demonstrate where the cited references teach a medical device "coated with the recited polymer matrix within which an enzyme of any type is disposed . . . and not merely coated or immobilized onto a solid substrate" (Br. 6[2]).

As Appellant explains "Van Antwerp discloses an enzyme bound to the surface of a catheter that is then coated with a polysilicone or starch based 'encapsulating coating'" (Br. 7; *see, e.g.*, Van Antwerp, col. 2, ll. 42-46 ("the selected enzyme is applied to indwelling surfaces of the catheter as a thin micellar coating. A porous encapsulant such as a porous silicone rubber film is then applied to the catheter to cover and encapsulate the micellar enzyme")). Thus, even if one were to modify Van Antwerp's catheter according to the teachings of Pinchuk, the resulting catheter would still not reach Appellant's claimed requirement that the enzyme is disposed within a matrix comprising a polyolefinic block copolymer. At best, the proposed modification addresses the composition of the medical article itself, e.g. the catheter, and not the matrix that is disposed on the article as recited in Appellant's claims. There is no teaching in Pinchuk that the block copolymers of polyolefin and styrene or acrylate be used to coat a medical device, e.g., a catheter. Rather Pinchuk directs one of ordinary skill in the

[2] All reference to the Brief (Br.) refers to the Brief received April 11, 2006.

art to make the medical device (the catheter) from the block copolymers of polyolefin and styrene or acrylate.

"Hendrickson discloses enzymes 'immobilized on the surface' of a fibrous support that is then 'coated' with a polymer" (Br. 7). Hendrickson's "invention provides a composite article comprising in sequence: (a) a woven or nonwoven fibrous support which has been subjected to a surface modification treatment . . . (b) a layer of a protein immobilizer compound, and (c) a biologically active protein, such as catalase" (Hendrickson, col. 5, ll. 3-13). Thus, even if one were to modify Hendrickson's composite article by substituting the woven or nonwoven fibrous support with Pinchuk's polymeric composition, the resulting article would still not reach Appellant's claimed requirement that the enzyme is disposed within a matrix comprising a polyolefinic block copolymer that is disposed on a medical article. Instead, the resulting article would be made of a polyolefinic block copolymer and would further comprise a layer of a protein immobilizer compound that is then coated with enzyme as is taught by Hendrickson.

For the foregoing reasons, we find that the combination of Hendrickson and Van Antwerp taken alone or in combination with Pinchuk fails to account for all the limitations of Appellant's claimed invention. Accordingly, we reverse the rejection of claims 1, 13-16, and 19-24 under 35 U.S.C. § 103(a) as unpatentable over the combination of Hendrickson and/or Van Antwerp taken with Pinchuk.

Claims 17 and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hendrickson, Van Antwerp, Pinchuk and Appellant's admitted prior art.

The Examiner relies on Hendrickson, Van Antwerp, and Pinchuk as discussed above. The Examiner recognizes, however, that none of these references teach the immobilization of enzymes on a medical article through antibody antigen interactions (claim 17) or by nucleic acid hybridization reactions (claim 18) (Answer 4). To make up for this deficiency, the Examiner relies on Appellant's disclosure that "these non-covalent protein-binding techniques are known [in] the art" (*id.*).

Based on these findings the Examiner concludes that "[i]t would have been obvious to use non-covalent attachment techniques to immobilize the enzymes taught by Hendrickson or . . . [Van] Antwerp . . . since these techniques are art known binding techniques, especially known to be used to coat medical articles" (*id.*).

The Examiner's rejection is deficient for two reasons. First, both of claims 17 and 18 depend from claim 11 which was not included in the rejection over the combination of Hendrickson and/or Van Antwerp taken with Pinchuk. Having failed to demonstrate that the references teach the limitations of claim 11, the Examiner has failed to establish a prima facie case of obviousness for claims 17 or 18 which depend from claim 11.

Second, the Examiner's reliance on Appellant's Specification fails to make up for the deficiency in the combination of Hendrickson and/or Van Antwerp taken with Pinchuk discussed above.

Accordingly, we reverse the rejection of claims 17 and 18 under 35 U.S.C. § 103(a) as unpatentable over the combination of Hendrickson, Van Antwerp, Pinchuk, and Appellant's admitted prior art.

Claims 1, 11-16, 19-24, and 27 stand rejected under 35 U.S.C.

§ 103(a) as unpatentable over the combination of Sivan and Pinchuk.

The Examiner finds that Sivan teaches a stent that comprises an enzyme either chemically attached to the stent or alternatively entrapped within a polymeric hydrogel that covers the stent (Answer 5). The Examiner recognizes that Sivan teaches the use of "polymers and copolymers such as polyethylene, polypropylene, polyacrylic acid and other" (*id.*). However, as Appellant points out, Sivan teaches that the stent, e.g., the medical article, itself is made from these polymers and copolymers not coated with a matrix of these polymers and copolymers (Br. 10; see Sivan, col. 3, ll. 61-65). The Examiner relies on Pinchuk to make up for Sivan's failure to teach the use of a "block copolymer comprising polybutylene and acrylates or vinyl aromatics" (Answer 5).

Based on this evidence the Examiner concludes that

> [t]he use of polymeric material made from block copolymers of polyolefin and styrene or acrylate in the medical devices of Sivan would have been obvious to one of ordinary skill in the art, with a reasonable expectation of success since Pinchuk teaches that these block copolymers are biostable and crack-resistant when implanted in vivo.

(*Id.*)

For the reasons set forth above with regard to the combination of Hendrickson and/or Van Antwerp taken with Pinchuk we disagree with the Examiner's conclusion of obviousness. As Appellant points out the combination of Sivan and Pinchuk would, at best, result in a stent made of Pinchuk's polymers, not a stent comprising an enzyme that is disposed within a matrix comprising a polyolefinic block copolymer that is disposed on a medical article.

Accordingly, we reverse the rejection of claims 1, 11-16, 19-24, and 27 under 35 U.S.C. § 103(a) as unpatentable over the combination of Sivan and Pinchuk.

Claims 17 and 18 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Sivan, Pinchuk, and Appellant's admitted prior art.

The Examiner relies on Sivan and Pinchuk as discussed above. The Examiner recognizes, however, that neither of these references teaches the immobilization of enzymes on a medical article through antibody antigen interactions (claim 17) or by nucleic acid hybridization reactions (claim 18) (Answer 6). To make up for this deficiency, the Examiner relies on Appellant's disclosure that "these non-covalent protein-binding techniques are known [in] the art" (*id.*).

Based on these findings the Examiner concludes that "[i]t would have been obvious to use non-covalent attachment techniques to immobilize the enzymes taught by Sivan . . . since these techniques are art known binding teachiniques, especially known to be used to coat medical articles" (*id.*).

The cited portion of Appellant's Specification fails to make up for the deficiencies in the combination of Sivan and Pinchuk discussed above.

Accordingly, we reverse the rejection of claims 17 and 18 under 35 U.S.C. § 103(a) as unpatentable over the combination of Sivan, Pinchuk, and Appellant's admitted prior art.

CONCLUSION

In summary, we reverse all rejections of record.

REVERSED

Ssc:

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